CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

October 11, 2002

H.R. 3580
Medical Device User Fee and Modernization Act

As passed by the House of Representatives
on October 9, 2002

SUMMARY

H.R. 3580 would amend the Federal Food, Drug, and Cosmetic Act to change the regulatory and approval process for medical devices. It would authorize the Food and Drug Administration (FDA) to collect fees to cover the cost of expediting the review of applications for approval to market medical devices. Such fees would be collected and made available for obligation only to the extent, and in the amount, provided in advance in appropriation acts.

H.R. 3580 would expand and reauthorize certain activities related to FDA's regulation of medical devices. It would allow FDA to accredit third parties to inspect U.S. manufacturing facilities of medical devices and to establish new labeling and data requirements for manufacturers that reprocess single-use devices. Regulated products that do not comply with FDA's labeling requirements would be deemed misbranded and firms would be subject to civil penalties.

H.R. 3580 also would authorize the creation of an office within FDA to oversee the review of applications for "combination products" and would authorize additional appropriations for FDA's surveillance of medical devices on the market.

CBO estimates that implementing H.R. 3580 would have a negligible effect on spending in 2003 and cost $36 million over the 2003-2007 period, assuming the appropriation of the necessary amounts. This estimate assumes that compliance with new labeling requirements would be widespread; thus, CBO estimates that revenues from civil monetary penalties would be negligible.

FDA's authority to assess user fees and operate the third-party inspection program would lapse unless appropriations for certain FDA activities reach specified levels. But the bill would not explicitly authorize additional funding, and the spending that would result is not included in CBO's estimate of the bill's costs. CBO estimates that $78 million in additional appropriations above baseline levels would be necessary between 2003 and 2007 to avoid early termination of the user fee program. A total of $5 million in additional funding over the five-year period would be necessary to maintain the third-party inspection program. Additional outlays would total $77 million.

Changes made to the regulation of medical devices by the bill could affect the prices of medical devices on the market over the next five years. If so, the costs of federal health programs that pay for medical devices would be affected. Although the direction of the potential effect of various provisions of H.R. 3580 on the average price of medical devices is highly uncertain, CBO anticipates that the magnitude of any such effect would likely be small.

H.R. 3580 would place a number of requirements on the manufacturers of medical devices, including the payment of fees. In some cases, state, local, or tribal governments could be manufacturers of those devices. Thus, those requirements would be both private-sector and intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). Because many of those requirements would depend on future actions of the Secretary of Health and Human Services (HHS), however, CBO cannot determine whether their direct cost to the private sector would exceed the annual threshold specified in UMRA ($115 million in 2002, adjusted annually for inflation) in any of the first five years the mandates would be effective. CBO estimates that the costs of those mandates to state, local, and tribal governments would be minimal.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 3580 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

BASIS OF ESTIMATE

For this estimate, CBO assumes that the bill will be enacted in the fall of 2002 and that outlays will follow historical spending rates for the authorized activities. Where H.R. 3580 specifies the amounts authorized to be appropriated, CBO assumes that such appropriations will be made. Where appropriations of such sums as necessary are authorized, CBO assumes that the estimated amounts will be provided for each fiscal year.

	By Fiscal Year, in Millions of Dollars				
	2003	2004	2005	2006	2007
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
Food and Drug Administration					
Estimated Authorization Level	6	11	11	13	13
Estimated Outlays	5	9	11	12	13
Collection of User Fees					
Estimated Authorization Level	-25	-29	-33	-38	-48
Estimated Outlays	-25	-29	-33	-38	-48
Spending of User Fees					
Estimate Authorization Level	25	29	33	38	48
Estimated Outlays	19	27	32	36	45
Other [1]					
Estimated Authorization Level	2	0	0	0	0
Estimated Outlays	1	*	*	*	0
Total Changes					
Estimated Authorization Level	8	11	11	13	13
Estimated Outlays	*	7	9	11	10
MEMORANDUM:					
Additional Appropriations for the CDRH Necessary to Avoid Sunset Provisions (User Fee and Third-Party Inspection Programs)[2]					
Estimated Authorization Level	18	17	16	16	15
Estimated Outlays	13	16	16	16	15

Notes: * = Less than $500,000.

CDRH = Center for Device and Radiologic Health.

1. H.R. 3580 would mandate that the General Accounting Office conduct a study on information provided to patients about the benefits and risks of breast implants and the Institute of Medicine report on FDA's surveillance of devices on the market used on pediatric populations.

2. These figures represent CBO's estimates of the minimum levels of additional appropriations (above baseline levels) that would be necessary for FDA to maintain authority to both collect user fees and allow third-party inspections of facilities for the manufacture of medical devices. Although the amounts are shown on an annual basis, the user fee program would sunset if cumulative appropriations do not equal the sum of the minimum levels for certain years. CBO estimates the cumulative amount would need to reach $64 million by 2006 in order for the program to continue in that year; an additional $13 million in funding for 2007 would be necessary to continue the program in that year. A total of $5 million in additional funding over the five-year period would be necessary to maintain the third-party inspection program.

Spending Subject to Appropriations

H.R. 3580 would extend, expand, and modify activities of FDA related to the regulation of medical devices. It would also create a new user fee program, allow third-party review of manufacturing facilities, establish an office of combination products in the Center for Device and Radiologic Health (CDRH) at FDA, and mandate new studies related to medical devices.

Title I. Title I would establish a new user fee program to help defray FDA's costs of expediting review of device applications. The user fee program would be authorized through 2007 and would take effect only to the extent, and in the amount, provided in advance in appropriation acts. The bill contains a schedule of appropriation targets, which, if not met or exceeded on a cumulative basis, would trigger the sunset of the user fee program before 2007. Title I would also authorize additional appropriations for FDA's surveillance of medical devices on the market. CBO estimates that implementing the provisions of title I would save $4 million in 2003 and cost $15 million over the 2003-2007 period, assuming appropriation of the necessary amounts.

User Fee Program. H.R. 3580 would require FDA to assess and collect fees from manufacturers for review of medical device applications, with the intent of expediting review of device applications. Aggregate amounts of such fees are specified for each fiscal year 2003 through 2007; those amounts may be adjusted for inflation, workload estimates, and other compensating factors. CBO assumes FDA would collect amounts specified in the bill increased by the inflation index for wages and salaries of federal workers. Such fees could be collected and made available for obligation only to the extent, and in the amount, provided in advance in appropriation acts.

CBO estimates that establishing the user fee program would save $6 million in 2003 and $15 million over the 2003-2007 period. Because FDA would have the authority to spend the collections, the estimated budget authority for collections and spending offset each other exactly, while the outlays lag behind collections and result in small savings each year.

FDA's authority to assess fees would expire at the end of 2005 unless cumulative appropriations for salaries and expenses of CDRH for the 2003-2006 period equal or exceed a specified amount ($205.7 million) adjusted for inflation. (The 2002 appropriation for CDRH is $181 million.) The bill would establish a similar requirement for continuing the assessment of fees in 2007. Because the bill would not explicitly authorize the appropriation of the amounts needed for FDA to continue to assess fees, the cost of these additional funds is not included in CBO's estimate for the bill. CBO estimates that $78 million in additional appropriations for CDRH, above baseline levels, would be necessary between 2003 and 2007 to avoid early termination of the user fee program. Additional outlays would total $73 million over that period.

Other Provisions. The bill would authorize an increase above amounts obligated in 2002 of $3 million in 2003, $6 million in 2004, and such sums as necessary thereafter, for FDA to expand surveillance of medical devices on the market, which includes tracking and responding to reports of adverse events. CBO assumes FDA's workload would increase under the bill as review times are reduced and devices come onto the market more quickly under the user fee program. The bill also would require FDA to report to the Congress on its performance under the user fee program and to consult with academic, manufacturer, and consumer groups before reauthorization of the program. CBO estimates that these provisions of title I would cost $2 million in 2003 and $30 million through 2007.

Title II. This title would establish third-party inspections of facilities that manufacture medical devices and a new office to oversee combination products (such as products that can be considered both a drug and a device). Other provisions would extend third-party review of certain device applications, modify how FDA reviews applications to market devices, and require FDA to report to the Congress on certain devices. CBO estimates that implementing those provisions would cost about $3 million in 2003 and $18 million over the 2003-2007 period, assuming the appropriation of the necessary amounts.

Third-Party Accreditation. Title II would establish a third-party inspection program for U.S. facilities that manufacture medical devices. To implement the program, FDA would issue guidance on accreditation criteria and conduct periodic audits of inspectors. FDA has some experience with this type of program in Europe, where third parties are allowed to inspect facilities but the practice is not widespread in all countries. FDA believes that companies in the United States would be more inclined to seek a third-party inspection than in Europe, which could make the program more popular here than abroad.

The bill would limit to 15 the number of organizations that FDA could accredit in the first year. But according to FDA, roughly 110 organizations exist world-wide that could apply for accreditation. FDA anticipates, however, that some would not qualify because of the conflict-of-interest standards specified in the bill.

CBO estimates that implementing this program would cost FDA less than $1 million in 2003 and $11 million over the 2003-2007 period. We anticipate that 15 organizations would be accredited in 2003 and 10 additional organizations would be accredited by 2005. We also assume that FDA would train and audit three people from each accredited organization, as it does in its European program.

H.R. 3580 would require FDA to maintain its current level of effort to carry out inspections. In addition, the third-party accreditation program would lapse if funding for inspections increases by less than 5 percent per year for any two consecutive years. (Over the 2003-2007 period, an increase of 5 percent per year over the 2002 level would add $5 million to funding above baseline amounts and result in additional outlays of $4 million.)

Office for Combination Products. Title II would require FDA to better coordinate its review of combination products. Under current law, the FDA staff identifies which center within the agency should take the lead in reviewing combination products, but it does nothing further to track or facilitate review of such products. H.R. 3580 would establish a new office to coordinate review between centers, resolve disputes, and track the disposition of applications for combination products.

CBO estimates that creating a new office would cost less than $1 million in 2003 and about $4 million over the 2003-2007 period. This estimate assumes more staff would be needed in the first two years to establish the data tracking systems and procedures of the new office.

Other Provisions. Title II would also extend by one year—through 2007—the authority of FDA to allow third-party review of premarket notification submissions.[1] To maintain this program, CBO assumes FDA would continue to issue guidance to persons seeking inspection and periodically audit reviewers who have been approved. The bill also would make permanent expiring provisions of the Federal Food, Drug, and Cosmetic Act that limit FDA's ability to hold or deny applications when an unapproved use of the device has been identified. Provisions of this title also would require FDA to accept and review partial applications from device manufacturers, expanding the scope of a current pilot project.

FDA would be required to use electronic technology to accept registrations from device manufacturers, when feasible. Currently, FDA does not have the data systems in place to accept electronic versions of 17,000 to 18,000 registrations a year. Finally, this title would require other administrative actions by FDA, such as reporting to the Congress on the timeliness of premarket reviews, including pediatric experts on review panels, and publishing information on the Internet. CBO estimates that implementing those provisions would cost less than $500,000 in 2003 and $1 million over the 2003-2007 period.

Studies. Under title II, the Comptroller General would conduct a study and report on information provided to patients who receive breast implants. The Secretary of HHS would be required to contract with the Institute of Medicine for a study of the effectiveness of surveillance of devices on the market that are used by children. CBO estimates those studies would cost $1 million in 2003 and $2 million over the 2003-2007 period. In addition, the bill would require the National Institutes of Health (NIH) to support

1. Before certain devices can be commercially distributed, manufacturers must submit a "premarket notification" to FDA showing the device to be safe and effective for use, or substantially equivalent to a device currently deemed to be safe and effective. "Premarket" means before the device is introduced into commercial distribution. FDA requires "premarket notification" for most devices and "premarket approval" for class III devices–those that sustain or support human life. Applications for premarket approval require a heightened level of scientific review to ensure the safety and effectiveness of class III devices.

research on breast implants. CBO estimates that the cost of the provision would be negligible because NIH recently completed a comprehensive breast implant study and continues to conduct research in this area.

Title III. This title would expand labeling and data requirements for medical devices. First, it would require manufacturers (including firms reprocessing single-use devices) to place their names or symbols on all devices. FDA could waive the requirement if it is not feasible or safe to label. According to industry and agency representatives, manufacturers of original devices already identify themselves on their devices, but firms reprocessing devices usually place their identification only on the package. In addition, the bill would require companies that reprocess single-use devices to state on their packaging that the device had been reprocessed. Products that do not comply with FDA's labeling requirements would be deemed misbranded and the firm would be subject to civil penalties.

Further, firms reprocessing devices would be required to submit validation data that describe the procedures used to clean, sterilize, and test the functional performance of most reprocessed devices. Under current law, class I and some class II devices are exempt from filing premarket notifications with the FDA. Under this bill, FDA would be required to identify the class I and II devices that would no longer be exempt from filing. (Device classes I, II, and III refer to the level of CDRH regulation of a given device.) Firms reprocessing those devices would be required to submit notifications and include the validation data described in the bill. Firms that have submitted or will submit premarket notifications for non-exempt devices would also be required to submit validation data for those devices.

Firms reprocessing class III devices would be allowed to submit "premarket reports" instead of premarket applications required under current law. Premarket reports as described in the bill are similar to premarket applications, except that they require less detailed information on the manufacturing specifications of the original device. Currently, the requirement for original specifications on class III devices has effectively barred companies from reprocessing class III devices because original manufacturers are reluctant to share this information. Firms reprocessing class III devices also would submit validation data with their premarket reports under this bill.

CBO believes the workload of FDA would expand in order to implement these provisions. For example, FDA would have to issue several guidance documents related to the labeling and identification of exempt devices. It also would need to review premarket notifications, reports, and validation data submitted as a result of the bill. According to FDA, the workload might be highest initially as currently exempt devices become nonexempt and as

the agency determines how to review validation data. CBO estimates that implementing these provisions would cost less than $1 million in 2003 and $4 million over the 2003-2007 period, assuming the necessary amounts are appropriated.

ESTIMATED IMPACT ON STATE, LOCAL AND TRIBAL GOVERNMENTS

H.R. 3580 would place a number of requirements on the manufacturers of medical devices and also require them to pay fees to the FDA for approval to market those devices. The bill would exempt state government entities from fees if the device will not be distributed commercially. In other cases, any state, local, or tribal government that manufactures medical devices would have to pay the fee and comply with other requirements in the bill. The fee and the other requirements of the bill would be intergovernmental mandates as defined in UMRA. However, CBO is unaware of any case in which a state, local, or tribal entity would be directly responsible for meeting these requirements or for paying the associated fees. Consequently, CBO estimates that any costs associated with the intergovernmental mandates would be minimal. Thus, the threshold established in UMRA ($58 million in 2002, adjusted annually for inflation) would not be exceeded.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

The bill contains a number of private-sector mandates as defined in UMRA on the manufacturers of medical devices. Because many of those requirements would depend on future actions of the Secretary of HHS, however, CBO cannot determine whether their direct cost would exceed the annual threshold specified in UMRA ($115 million in 2002, adjusted annually for inflation) in any of the first five years the mandates would be effective.

Subject to approval in an appropriation act, title I of the bill would give the Secretary the authority to assess and collect user fees from manufacturers of medical devices to defray the cost to the FDA of reviewing applications for approval to market those devices. In 2003, the fees would be $139,000 for each premarket application, premarket report, and panel track supplement that FDA reviews, and about $2,400 for each premarket notification submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act. Those fees would constitute mandates on the manufacturers. CBO estimates that the direct cost of those mandates would be $25 million in 2003, rising to about $48 million in 2007.

Section 206 of the bill would require manufacturers of medical devices to submit their registrations electronically. Under current law, manufacturers of medical devices are required to register annually with FDA, and under other circumstances as specified by law. Those registrations are submitted on paper forms. Under H.R. 3580, if the Secretary found

that electronic registration was feasible, then manufacturers would be required to submit all of their registrations electronically unless the Secretary granted a waiver to a particular manufacturer. While the requirement to submit registration electronically, rather than on paper forms, is a private-sector mandate, CBO cannot estimate its cost because it is uncertain when, or if, the Secretary would find that such electronic registration was feasible. FDA currently receives between 17,000 and 18,000 registrations per year, all on paper forms. If required to file electronically, manufacturers would incur a largely one-time cost for changing to electronic registration, but in the long run, electronic registrations could be less costly to submit than paper forms.

Section 301 of the bill would require manufacturers of medical devices to label each device with the name of the manufacturer or an abbreviation or symbol of the manufacturer, unless the Secretary determined that compliance with the requirement was not feasible for the device or would compromise its safety or effectiveness. Under current law, manufacturers are required to put their names on the packaging of a device, but not on the device itself. Thus, the requirement is a private-sector mandate as defined in UMRA. The mandate would affect both manufacturers of original equipment and firms that reprocess single-use devices. According to the FDA, there are currently about 75,000 types of medical devices on the market, and about one-third of those are not labeled with the name or symbol of the original manufacturer. In most cases, this is because the device is too small to permit the manufacturer to label it. For this reason, CBO assumes that most manufacturers of devices that do not currently comply with the requirements in the bill would be eligible for a waiver. Industry experts also state that the vast majority of reprocessed medical devices bear an adhesive or laser-etched label on the device that identifies the reprocessing firm. Thus, CBO estimates that the overall cost of complying with the mandate would be small.

Section 302 of the bill contains a number of private-sector mandates. It would require firms that reprocess single-use devices to place a statement on the device's label that identifies the device as a reprocessed device for single use and identifies the reprocessing firm. According to industry experts, the labels of most reprocessed single-use devices already contain this statement; thus, the cost of complying with this mandate would be minimal.

Section 302 also would require firms that reprocess single-use devices to submit validation data that detail the procedures used to clean, sterilize, and assess the functional performance of those devices to demonstrate that the reprocessed device is substantially equivalent to its predicate device after the maximum number of times the device will be reprocessed. In the case of reprocessed single-use devices that, under current law, are exempt from submitting a premarket notification submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act, the bill would require the Secretary to develop a list of devices that would no longer be exempt because they are critical or semi-critical single use devices (that is, they

contact mucous membranes or areas of the body that are sterile under normal conditions). The manufacturers of those devices would be required to submit both a premarket notification submission under section 510(k) and the validation data described above.

Because the Secretary has the authority, under current law, to determine which devices are exempt from premarket notification requirements, the provision in the bill that would require manufacturers to complete a premarket notification submission is not a new private-sector mandate. However, the provision in the bill that would require manufacturers to submit validation data is a new mandate. CBO estimates that approximately 120 types of reprocessed single-use devices are currently exempt from premarket notification requirements. According to the FDA, about 70 of those device types are likely to meet the definition of critical or semi-critical single-use devices specified in the bill. If the Secretary revoked the exemptions of each of those device types, CBO estimates that the cost of submitting validation data would be approximately $50 million in the first year that the mandate was effective. The cost of the mandate could be substantially different, though, depending upon the actions of the Secretary.

In the case of reprocessed single-use devices that, under current law, are required to submit a premarket notification submission under section 510(k) of the act, the Secretary would review those submissions (including those already approved prior to enactment of the bill) and publish a list of reprocessed single-use devices for which validation data, as described above, is required to ensure that the reprocessed device is substantially equivalent to a predicate device. Manufacturers of those devices selected by the Secretary would be required to submit validation data within nine months. The requirement to submit validation data is a private-sector mandate. CBO estimates that there are about 80 types of reprocessed single-use devices that are required to submit a premarket notification under current law and, thus, might be required to submit such validation data if the provision were to become law. However, since the Secretary would have discretion to choose which of those devices would require validation data, CBO cannot estimate the cost of complying with this mandate.

ESTIMATE PREPARED BY:

Federal Costs: Shawn Bishop, Julia Christensen, and Chris Topoleski
Impact on State, Local, and Tribal Governments: Leo Lex
Impact on the Private Sector: Jennifer Bowman

ESTIMATE APPROVED BY:

Robert A. Sunshine
Assistant Director for Budget Analysis